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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,431	12/14/2000	Richard S. Ginn	258/2999	1012

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EXAMINER

NERBUN, PETER P

ART UNIT	PAPER NUMBER
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3765

DATE MAILED: 06/24/2003

19

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/738,431

Applicant(s)

GINN ET AL.

Examiner

Peter P Nerbun

Art Unit

3765

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39,40,44-47,52-55,60-68,80 and 82 is/are pending in the application.
- 4a) Of the above claim(s) 45-47,64 and 80 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 39,40,44,52-55,60-63,65-68 and 82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 39-44, 52-55, 60-63, and 65-68 are rejected under 35 U.S.C. 102(a) as being anticipated by Shchervinsky et al, newly cited. The patent to Shchervinsky et al discloses an apparatus for sealing a passage through tissue 12, Fig. 6 comprising an elongate shaft 20, Fig. 6 having a proximal end and a distal end, and a plug member 28, Fig. 6 disposed on the distal end of the elongate shaft, the elongate shaft having a cross-section that is substantially smaller than a cross-section of the plug member, wherein said plug member and said elongate shaft have a lumen therein (note the filler 32, Fig. 6 that can be injected into the lumen) which extends from the distal end of said plug to the proximal end of said elongate shaft. With regard to claims 54 and 67, the end of syringe 30, Fig. 6 constitutes a seal for selectively sealing the lumen 20, Fig. 6.

Claim 82 is rejected under 35 U.S.C. 102(b) as being anticipated by Frassica, newly cited. The patent to Frassica discloses an apparatus comprising an elongate member 502, Fig. 31A having a proximal end and a distal end, and a plug member 501, Fig. 31A substantially permanently attached to the distal end of the elongate shaft, the plug member comprising a helical thread 503, Fig. 31A on its outer surface, the elongate member having a cross section that is substantially smaller than a cross section of the plug member, wherein said plug member and said elongate shaft have a

Art Unit: 3765

lumen 508, Figs. 30, 31A therein which extends from the distal end of said plug to the proximal end of said elongate shaft. With regard to the preamble of claim 82 where applicant recites the manner in which the apparatus is intended to be employed (viz. "for sealing a passage through tissue") it has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

Claims 45-47, 64, and 80 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 13.

Applicant's arguments with respect to claims 39, 60, and 82 have been considered but are moot in view of the new ground(s) of rejection. The examiner has determined that claims 45-47, 64, and 80 are drawn to a non-elected species. Applicant states that claim 80 has been amended to recite the presence of a lumen extending from the distal end of the plug to the proximal end of the elongate shaft. Because of this recitation applicant concludes that claim 80 reads upon the elected species illustrated in Fig. 3. The examiner disagrees because claim 80, lines 5-6 recites "a plug member releasably secured to the distal end of the elongate member by the connector". On page 15, lines 8-9 of the specification applicant describes the Figure 4 embodiment by stating that: "*Unlike the previous embodiment*, however, the plug member 220 is releasable from the shaft 212" (emphasis added). The "previous embodiment" that applicant refers to is the embodiment illustrated in Figure 3 which applicant elected in

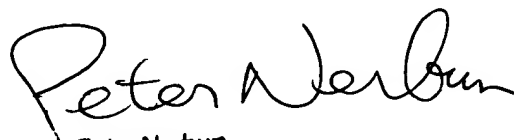
paper no. 13. Therefore the plug member 220 is disclosed as not being releasable from the shaft in the Figure 3 embodiment which means that claim 80 does not read upon the elected embodiment as disclosed. The same comment applies to claims 45-47. With regard to claim 64, applicant does not disclose that Figure 3 illustrates an apparatus in which intestinal mucosa is used as one of a hemostasis-promoting material and an infection-resistant material. Figure 2 is the only embodiment where applicant discloses intestinal mucosa as being used for this purpose. The disclosure of intestinal mucosa appears on page 12, lines 16-19.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Peter P Nerbun whose telephone number is 703-308-0955. The examiner can normally be reached on M-F (1st Week) M-Th (2d Week).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John J Calvert can be reached on 703-305-1025. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0758 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0861.

Peter Nerbun
June 19, 2003


Peter Nerbun
Primary Examiner